

Attorney Docket No.: **DEX-0176**
Inventors: **Ali et al.**
Serial No.: **09/787,844**
Filing Date: **August 6, 2001**
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REMARKS

Claims 8, 9, 13-15, 17-19, 21, 23, 24 and 26-45 are pending in the instant application. Claims 8, 9, 13-15, 17-19, 21, 23, 24 and 26-45 have been rejected. Claims 8, 14, 18, 23 and 26 have been amended. Claims 13, 17 and 21 have been canceled without prejudice. Support for these amendments is provided in the specification at 4, lines 26-28. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Objection to Claims 13, 17 and 21

Claims 13, 17 and 21 have been objected to as being dependent claims which do not further limit the base claim from which they depend. The Examiner suggests that claims 8, 14 and 18 from which claims 13, 17 and 21 depend state "the native protein encoded by SEQ ID NO:1" which is amino acids 14-327 of SEQ ID NO:2.

Claims 13, 17 and 21 have been canceled without prejudice thus mooted the Examiner's objection.

Withdrawal of this rejection is therefore respectfully requested.

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**II. Rejection of Claims 8, 9, 13-15, 17-19, 21, 23, 24 and
26-45 under 35 U.S.C. 112, first paragraph - Lack of
Enablement**

Claims 8, 9, 13-15, 17-19, 21, 23, 24 and 26-45 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Arguments presented in the last response were not found persuasive as the Examiner suggests that Applicants argue with a disclosure not presented in the specification as originally filed. In particular, the Examiner suggests that the specification as originally filed does not disclose that polypeptide comprising amino acids 14-327 of SEQ ID NO:2 is the native protein.

Applicants respectfully traverse the rejection.

At the outset, it is respectfully pointed out that claims 13, 17 and 21 inclusive of the phrase "amino acids 14-327 of SEQ ID NO:2" have been canceled without prejudice.

Applicants respectfully disagree with the Examiner's suggestion that the "nature of the invention is drawn to a method of imaging a gynecologic cancer using a monoclonal antibody or polyclonal antibody which specifically binds to

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SEQ ID NO:2 (claims 8, 13) . . ." The invention herein is drawn to the identification of the cancer specific gene (CSG) Pro104, defined at page 4 of the instant specification to refer to the native protein expressed by the gene comprising the polynucleotide sequence of SEQ ID NO:1, the native mRNA encoded by the gene comprising the polynucleotide of SEQ ID NO:1 or levels of the gene comprising the polynucleotide sequence of SEQ ID NO:1, being a diagnostic marker for gynecologic cancers and that antibodies thereto can be used in imaging gynecologic cancers.

It is clear from claim 8, 14, 18, 23 and 26, that the invention is not drawn to a monoclonal antibody or polyclonal antibody which specifically binds to SEQ ID NO:2, bur rather to a monoclonal antibody or polyclonal antibody which specifically binds a native protein of SEQ ID NO:1. Applicants have amended claims 8, 14, 18, 23 and 26 herein to recite "the native protein expressed by SEQ ID NO:1" in accordance with language of the specification at page 4, line 27.

Applicants also respectfully disagree with the Examiner's suggestion that previous arguments regarding

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identifying the ORF and expressed protein of a nucleic acid sequence were unpersuasive because Applicants argue with a disclosure not presented in the specification as originally filed.

MPEP 2164.05(a) states that the specification need not disclose what is well known to those skilled in the art, and preferably omits that which is well known to those skilled in the art and already available to the public. As made clear in Applicants' last response, the methods and means for identifying the ORF and native protein expressed by a nucleic acid sequence, such as SEQ ID NO:1, were well known to those skilled in the art as of the filing date of the instant application and therefore need not be presented in the specification as originally filed.

Further, MPEP 2164 is clear; the invention that one of skill in the art must be enabled to make and use is that defined by the claims of the particular application or patent.

The invention is a method of imaging a gynecological cancer using a monoclonal or polyclonal antibody which specifically binds a CSG. Antibodies are characterized in the specification on page 7 lines 1-18 and page 12 lines 5-

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7. A CSG is defined in the specification as being "native protein expressed by the gene comprising the polynucleotide sequence of SEQ ID NO: 1" on page 4 lines 26-28. Examples 1 and 2 in the specification characterize the CSG given the name Pro104 (SEQ ID NO: 1). As outlined above, the CSG "Pro104" described in the specification comprises the native protein expressed by the gene comprising the polynucleotide sequence of SEQ ID NO: 1. Claims 8, 14, 23 and 26 have been amended to specifically recite "native protein expressed by SEQ ID NO: 1...". Therefore, the instant claims, drawn to a method of imaging a gynecologic cancer comprising contacting a cell with a polyclonal or monoclonal antibody which specifically binds the native protein expressed by SEQ ID NO:1 and detecting bound polyclonal or monoclonal antibody indicative of the presence of a gynecologic cancer, are disclosed and enabled by the application as filed.

Withdrawal of this rejection under 35 U.S.C. 112, first paragraph is respectfully requested.

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**III. Rejection of Claims 8, 9, 13-15, 17-19, 21, 23, 24
and 26-45 under 35 U.S.C. 112, first paragraph - Written
Description**

Claims 8, 9, 13-15, 17-19, 21, 23, 24 and 26-45 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The Examiner suggests that the specification as originally filed does not disclose that polypeptide comprising amino acids 14-327 of SEQ ID NO:2 is the native protein.

It is respectfully pointed out that all claims inclusive of the phrase "polypeptide comprising amino acids 14-327 of SEQ ID NO:2", in particular claims 13, 17 and 21, have been canceled without prejudice, thus rendering moot this rejection.

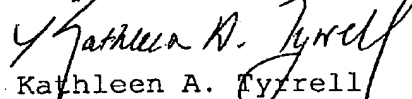
Withdrawal of this rejection under 35 U.S.C. 112, first paragraph is therefore respectfully requested.

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IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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